Carle Foundation Hospital

Carle Foundation Hospital
611 West Park Street
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir or Madam:

Enclosed you will find a copy of our organizations comments on the Draft Guidance for Hospital Bed System Dimensional Guidance to Reduce Entrapment #1537.

Thank you for providing the opportunity to address this important patient safety concern.

Sincerely,

Kathryn Tredway RN, BS

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Foundation Quality-PI Facilitator

2004D-0313

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Draft guidance for Industry and FDA Staff: Hospital Bed system Dimensional Guidance to Reduce Entrapment. #1537

Request for comments: 1. Exclusions-Framed flotation therapy products and bed systems using powered air mattress replacements.

- Air fluidized therapy beds – Tabled air fluidized therapy beds should be excluded. These beds are framed and should not pose any threats. Overlays, however, should have the recommended dimensional limits.
- Bariatric (obesity) beds, pediatric beds and infant cribs should be measured as a separate patient population. The anthropometric measurements needed to determine the design requirements for these beds and stretchers not used for extended stay must be determined. These patients, the obese and pediatric populations, are at risk for entrapment, as well. Consider that the American population now weighs an average 24 pounds heavier than 50 years ago and that 50% of the American population is overweight/obese. The importance of these beds cannot be overlooked.
- Stretchers not intended for use as a bed are sometimes used in Emergency Departments as an extended stay device for a patient while they are waiting for a room. Patients in these beds are not always watched as closely because the staff is busy with all the other patients. Patients are also wheeled on a stretcher from their room to radiology or the lab and they may stay on the bed unattended by the "transport" person or the receiving person.

  Even though there may be not instances of entrapment (?) in one of these devices, the dimensional guidelines for reducing entrapment should be implemented throughout the hospital bed and "device" system. All manufacturers of "beds" and hospital "devices" should adhere to the standards to prevent entrapment. No patient should ever die of entrapment in a bed device due to asphyxiation. There is increased risk for entrapment for patients who use these devices due to body size and reduced body movement.

Partial Exclusion from the scope of this guidance:

- Kinetic treatment tables and rotation beds: The dimensional limits must be adhered to within the perimeter of the rail.

Request for comments: 2. More stringent dimensional limit at Zone 2.

- Yes, the FDA should modify its recommendation to recommend a dimensional limit of less than 2-1/3 inches (60mm) for all of the reasons listed in the guidance.
- Recommendations should also include replacement mattresses. By the time they are replaced, and it could be years, the replacement mattress may not conform to the guidelines. Makers of replacement mattresses should have the evaluation equipment and assessment checklist available for the buyer of

a new mattress to replace an existing one to help them stay within the new guidance guidelines.

Request for comments: 3. More stringent dimensional limit at Zone 3.

- Yes, the FDA should modify its recommendation to recommend a dimensional limit of less than 2-1/3 inches (60mm) for all of the reasons listed in the guidance.
- Mattress gets compressed and gap widens. Also, a child's head could fit through the 4-3/4" hole.

Request for Comments: 4. Recommendations for a dimensional limit for Zone 5.

- Yes, recommendations should have less than and greater than specifications for the dimensional limit at zone 5, especially since most hospital beds have the split rail configuration:
- < 2-1/3" (60mm) and > 12-1/2" (318mm) and an angle greater than 60 degrees in the V-shaped spaces between the rails.
- The extended care population is most at risk for entrapment in this zone. Many years will pass before a nursing home facility receives one of the new beds that will be manufactured in 2005 and beyond to conform to the guidelines contained in this guidance. Extra diligence must be exercised with end users of legacy beds that have been involved in entrapment episodes and will be available for use in extended care facilities for many more years.

Request for Comments: 5. Recommendation for dimensional limits for Zone 6.

- Yes, the FDA should include a dimensional limit for zone 6:
- Head: < 2-1/3" (60 mm) and angle > 60 degrees between upper (head) side rail and edge of headboard
- Foot: < 2-1/3" (60 mm) and angle > 60 degrees between lower (foot) side rail and edge of footboard

Request for Comments: 6. Recommendation for dimensional limits for Zone 7.

- The FDA is specifically requesting data on entrapment reports or near-miss entrapment events that may have occurred in Zone 7, including any details on these events and their frequency.

Request for Comments: 7. Articulated bed positions.

- Are you aware of entrapment events or near-entrapment events occurring when the bed is articulated? No.

- Do you believe entrapments only occur in the flat deck position? NO
  Beds do not generally stay in the flat deck position. If the angle of the bed produces a higher risk for entrapment, then we must find the solution to make bed angle a non-issue. That solution could be entrapment mitigating solutions already in place by the manufacturer.

Additional Request for Comments: 8. Application of this guidance to all health care settings.

- Many legacy beds in the health care system are the culprits in bed entrapments. This guidance document should apply to all hospital beds used in all care settings: acute care, long-term care, and in home-care settings. As a result of assessment of patient needs, and consideration of entrapment risk, legacy bed overseers will know more and will be more likely to comply with the guidelines for the patient's safety.

Appendix A: List of Hospital Bed Safety Workgroup (HBSW) Participating Organizations

The list of Hospital Bed Safety Workgroup participating organizations is extensive; however, the we do not see the American Medical Association listed. If doctors are the ones who determine level of restraint, then they should be involved in the decision making process of bed guidelines and assessment, in addition to their area of expertise: drug use involving physical or chemical restraint. In 1999, the AMA in the March/April issue of *Archives of Family Medicine,* called for increased research into use of restraints and widespread educational programs for health professional and consumers to improve awareness of the risks and benefits. Environmental adaptations such as hydraulic beds, that lower closer to the floor, mattresses that keep people from rolling out of bed and Velcro releases, that residents can control, were used at that time by nursing homes in Minnesota. The doctors had an interest then and probably still do now.

Appendix F: Hospital Bed Safety Workgroup: It is important to remember that many nursing homes are small operations, without access to the resources needed to implement the guidelines. Since a majority of the population of patients at risk for entrapment; the aged, frail, mentally incompetent and medicated are residents in nursing homes, extra care needs to be taken to notify nursing home owners, and to provide encouragement for compliance with the new industry guidelines.